



Declaration of Conformity
According to ISO/IEC 17050



Manufacturer's Name & Address:

SonoSite, Inc.
21919 - 30th Drive SE
Bothell, Washington 98021-3904 USA

European Authorized Representative's Name & Address:

SonoSite, Ltd.
European Headquarters
Alexander House, 40A Wilbury Way, Hitchin, Herts, SG4 0AP UK

Declares that the CE-marked product(s):

Item	Part Number(s)	GMDN Code	Manufacturer
SonoSite M-Turbo™ ultrasound system	P08189, P08241, V08189	40761, 40762, 40763, 40764	Manufactured by SonoSite, Inc.
SonoSite M-OB/GYN Office™ ultrasound system	P08189	40761, 40762, 40763, 40764	Manufactured by SonoSite, Inc.
SonoSite M-MSK™ ultrasound system	P08189	40761, 40762, 40763, 40764	Manufactured by SonoSite, Inc.

Complies with:

European Community Council Directive (Medical Device Directive) 93/42/EEC, Annex II, and are Class IIa devices in accordance with Annex IX, Rule 10. EC Certificate 02429 has been issued by the British Standards Institution for compliance with Annex II, section 3.2 of the European Council Directive 93/42/EEC. In addition, that said products comply with the applicable requirements of:

Safety:

- | | |
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| <ul style="list-style-type: none"> • EN60601-1: 1990, 2nd Edition including Amendment 1 and 2 • EN60601-1-1: 2001 | <ul style="list-style-type: none"> • EN60601-2-37: 2001 + A1 (2004) |
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EMI / EMC:

- EN60601-1-2:2007

Supplementary Information:

Included are the following Accessories and OEM Products:

Accessories:

AC Power Supply
Battery Pack
Biopsy/Needle Guides
ECG Cable, ECG Adapter
H Universal Stand
Mini Dock
PowerPack
PowerPark
SiteLink Image Management System
SonoCalc® IMT
C11x/8-5 Transducer
C60x/5-2 Transducer
D2x/2 Transducer
HFL38x/13-6 Transducer
HFL50x/15-6 Transducer

ICTx/8-5 Transducer
L25x/13-6 Transducer
L52x/10-5 Transducer
L38x/10-5 Transducer
L38xi/10/5 Transducer
P10x/8-4 Transducer
P21x/5-1 Transducer
SLAx/13-6 MHz Transducer
SonoSite Workflow Solutions
TEEx/8-3 Transducer
Triple Transducer Connect Module
Wireless Kit

OEM Products:

Aquasonic 100 Acoustic Gel
CIVCO, Transducer covers
Linemaster SP-997-216 Footswitch

National Display, 15" Flat Panel Display
Panasonic, DVD Recorder, LQ-MD800
Sony, Black and White Video Printer, UP897MD
Sony, Color Video Printer, UP-21MD
Sony, Digital Video Recorder, GV-D800
Sony, DVD Recorder, DVO-1000MD
Sony, External color monitor, PVM14M2-MDU
SparkLAN, USB WIRELESS DONGLE,
54MBPS, 802.11G, WL-685R
Symbol, Bar Code Scanner, DS6707-
SR20007ZZR
Symbol, Bar Code Scanner, USB, LS2208-
SR20007R-UR
Toroid Corp. Isolation Transformer

Quality Management and Quality Assurance:

- ISO 9001:2008 Quality management systems -- Requirements International Organization for Standardization
- ISO 13485:2003, Medical devices – Quality management systems – Requirements for regulatory purposes

Mary K. Moore

August 16, 2010
Bothell, Washington USA

Mary K. Moore
Vice-President, Regulatory Affairs